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PATENT  
Docket SU 103 US

In re: Application of Michael J. Precopio

Serial No. 10/519,972  
Filed: 12/23/2004

Examiner: Neil Levy  
Art Unit: 1615

Title: METHODS FOR TREATING ECTOPARASITE INFECTIONS ON THE  
MAMMALIAN BODY

FAX CERTIFICATION

I hereby certify that this correspondence is being telefaxed to: Commissioner for  
Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450; on 06/04/2007  
at fax number 571-273-8300.

Date: 06/04/2007

  
Signature of certifier

Henry E. Millson, Jr.  
Printed or typed name of certifier

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR 1.132

Michael J. Precopio hereby declares that: He was granted a Bachelor of Arts  
degree in chemistry with a minor in business administration from the University of  
Delaware in 1982; He has been President of Summers Laboratories, Inc. for the past 20  
years, and currently holds that position;

He is the sole inventor of the invention set forth in U.S. application Serial No.  
10/519,372, entitled METHODS FOR TREATING ECTOPARASITE INFECTIONS ON  
THE MAMMALIAN BODY.

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The following two studies were carried out under his supervision and control;

The compositions used in both of the studies had the following components:

<u>Component</u>	<u>% by weight</u>
Purified water	84.25
Benzyl alcohol, NF	5.00
Mineral Oil 5LT, NF	5.00
SPAN® 80, NF (sorbitan mono-oleate)	2.50
TWEEN® 80 NF (polysorbate 80)	2.50
CARBOPOL® 934 P, NF (carboxy polyethylene)	0.25
TROLAMINE® NF (triethanolamine)	<u>0.50</u>
	100.00

#### STUDY 1

An evaluator-marked, comparative, parallel, single-site study was carried out to evaluate the efficacy and safety of the above composition as a lice asphyxiator for the treatment of head lice.

The hair and skin on the heads of eighty-one (81) subjects, both males and females between the ages of 2 and 70 having a active infestation of *Pediculus capitis* (head louse) with at least 3 live lice and 10 eggs were topically treated with the above composition for 10 minutes, after which the composition was rinsed off with water, followed by another similar 10 minute treatment one week later. Seventy-nine subjects completed the study.

The primary efficacy measurement was the percentage of subjects who were confirmed as a treatment success based on the presence or absence of live lice.

At the end of the study (day 15 of the study), a 70% overall treatment success resulted (primary efficacy).

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A kill rate (%) was also determined which is the total number of lice minus the number of live lice over the total number of lice.

At the end of the study (day 15 of the study) the kill rate was 89%.

## STUDY 2

An identical study to that of Study 1 above was carried out except that forty-four (44) subjects, both males and females between the ages of 2 and 70 having an active infestation of *Pediculus capitis* (head louse) with at least 3 live lice and 10 eggs were used in the study, and the quantity of the composition was adjusted for each subject so that complete saturation of the entire length of each subjects hair was obtained.

At the end of the study (day 15 of the study), a 100% treatment success resulted (primary efficacy).

The results of the above studies shows that complete saturation of the entire length of each subject's hair is essential to obtain the very high treatment success (100%) and kill rate (greater than 99%) found in Study 2.


The results obtained in Study 1 were found to have resulted from incomplete saturation of the entire length of the long hairs in the subject population of that study.

The above finding, i.e. that the entire lengths of the subject's hair must be completely saturated with the compositions of the invention to obtain very high treatment success and kill rates, was unexpected and unobvious.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

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statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

  
Michael J. Proctor  
June 4, 2007  
Date